REMARKS

This amendment responds to the Office Action dated May 5, 2005, in which the Examiner finally rejected claims 17-18 and 20-21, claims 1-16 having previously been withdrawn from consideration, and claim 19 having been cancelled. Applicants have amended claims 17 (and thus dependent claims 18, 20, and 21), and have presented new claim 22. Reexamination and reconsideration is respectfully requested in light of the foregoing amendments and the following remarks.

The Anticipation Rejections

The Examiner has rejected claims 17, 18, and 20 under 35 U.S.C. section 102 (b), as allegedly being anticipated by Roberts. The Examiner asserts that Roberts teaches use of imidazole-4-acetic acid for inducing analgesia in a warm blooded animal. The Examiner admits that the reference makes no mention of modulating an immune response, but nevertheless argues that such a property or characteristic must be inherently presented in the referenced method. Since the administration of the same compound to the same population group would inherently possess the claimed therapeutic utility, the reference allegedly anticipates the claimed invention even absent explicit recitations of the mechanism of action.

Applicant respectfully traverses and requests reconsideration of this rejection, as applicants respectfully submit that the Examiner's strenuous reliance on the inherency doctrine is misplaced. The present invention is a method claim drawn to a new use for a known compound, and as such is patentable subject matter under well settled law.

unless the new use would have been obvious to a person of ordinary skill at the time the invention was made. 35 U.S.C. § 103(a). The unappreciated, newly discovered property of a compound that cannot be discerned from a fair reading of a reference simply is not anticipated by that reference where it fails to disclose that hitherto unappreciated use. While such a discovery of a new use for a known composition may not render the composition itself patentable, it certainly does not defeat the patentability of a claim drawn to the use of the composition, where as here, the use was simply unknown prior to applicants' discovery. For example, minoxidil was widely prescribed and sold to patients suffering from high blood pressure. Notwithstanding that, an additional patent was later issued for the newly discovered use of minoxidil as a treatment for male pattern baldness, even though hirsutism was a known side effect of monoxidil. Undoubtedly, some percentage of the men taking minoxidil for high blood pressure grew back hair on their bald spots, but this "inherent" effect of minoxidil did not preclude the later issuance of a patent to the new use or method for treating baldness. This unobvious new use for the known composition was found to be patentable. The same result should apply here.

Reconsideration and withdrawal of the anticipation rejection based upon Roberts is respectfully requested.

Likewise, the rejection of the amended claims based upon Schneider also seems misplaced. The Examiner asserts that Schneider teaches use of a composition comprising glycine for treatment of acute or chronic graft rejection by modulating tumor necrosis factor levels. The Examiner concedes that Schneider does not specifically mention the activity of glycine, which the Examiner asserts is an oxidation product of

urocanic acid. Nonetheless, the Examiner contends that in modulation of an immune response in an animal, such property or characteristic must be inherently presented in the referenced method. The Examiner further asserts that since the administration of the same compound to the same population would inherently posses the claimed therapeutic utility, the reference would thus anticipate the claimed invention even absent explicit recitation of the mechanism of action.

Applicant respectfully traverses this rejection as well, and maintains that the claimed method is neither anticipated nor rendered obvious by Schneider. The Examiner appears to posit that since glycine is an oxidation product of urocanic acid, and since Schneider discloses glycine for use in suppressing TNF and thereby suppressing acute or chronic graft rejection, it follows that Schneider anticipates the claimed invention. The Examiner cites no reference that shows that urocanic acid would be metabolized into glycine, and even should this occur, it does not necessarily follow that the amount of glycine so produced would have an immune suppressing effect. Schneider, for example, suggests a preferred daily dosage of 1 to 80 grams of glycine, in order to obtain the desired result. Further, there is no showing that TNF is present in the immune responses addressed by applicants' invention. By all accounts, it seems that here, as with the prior rejection, the Examiner has misapplied the doctrine of inherency as it relates to the law of anticipation. Here again, it is undisputed that discovering a new use for a known compound is patentable, where the use is unobvious. The Examiner has not shown that glycine, as opposed to the compositions claimed in the method are responsible for the anti-inflammatory effect of the method. Thus, the anticipation rejection based upon Schneider is misplaced and should be

withdrawn.

The Section 112 Rejections

The Examiner has rejected claim 17 under 35 U.S.C. section 112, first paragraph, asserting that while the specification is enabling for a method of reducing hypersensitivity with imidazole-4-carboxaldehyde, imidazole-4-acetic acid or imidazole-4-carboxylic acid, it does not reasonably provide enablement for a method of modulating an immune response with a product of oxidation of urocanic acid with a reactive oxygen species or a salt thereof or imidazole-4-carboxaldehyde, imidazole-4-acetic acid or imidazole-4-carboxylic acid. The Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to practice the invention commensurate in scope with these claims.

In response, applicants have added claims 23-24 for a method of reducing hypersensitivity as suggested by the Examiner (for which the applicants appreciate the guidance), but continue to maintain that the amended claim 17 meets the enablement strictures of section 112, first paragraph. As the Examiner well knows, the law of enablement does not require that applicants enable each and every species encompassed with the claimed genus, nor must the application set forth detail about knowledge ordinarily known to the skilled artisan. First, it was well-known that hypersensitivity is an immune response, and the way to treat an undesirable immune response was to administer an agent that would modulate it or suppress it. Second, the claims as amended do not encompass an unlimited number of species. Rather, they are broad enough to cover that which the inventor considers his invention, consistent

with the requirements of section 112 and the prior art.

Further, the present invention provides a novel mechanism and insight into a particular aspect of the workings of the immune system, see page 4, lines 14-16. The inventors elucidated the mechanism behind a natural immune suppressive response of the skin to oxidative stress, and subsequently identified compounds that are responsible in this pathway. The mechanism and the corresponding role of the compounds in the body were not known prior to the invention. The inventors discovered that an oxidation product of urocanic acid is responsible for the observed immune suppressive effect. The inventors unexpectedly discovered that several, not one, oxidation products have this effect. In addition, the inventors have characterized a series of compounds that have this immune suppressant effect both individually and in combination.

It is therefore respectfully submitted that this invention can be practiced by a person skilled in the art. The claims define the class of compounds, and the application includes data about activity in an animal for a representative number of the compounds. This amply meets the test for enablement. As stated above, not every species within a genus needs to work, nor does an inventor need to test or provide data for every conceivable species in order to claim a broader genus. Applicants submit, therefore, that they have met the requirements for enablement, and respectfully request that the rejection under section 112, first paragraph be withdrawn.

The Specification

The Examiner has restated his rejection to the specification, concerning Table 4, which he asserts is mentioned in several places but does not seem to be included in the specification. Applicants respectfully request the Examiner's continued indulgence

while applicants consider their alternatives, and requests that the Examiner permit applicants to continue to defer action. Applicants appreciate the Examiner's patience.

The Examiner has also requested correction of page 19, relating to Fig. 4. Applicants have made the correction, and submit that they have complied with the request, rendering it moot.

The Commissioner is hereby authorized to charge any fees which may be required in consideration of the filing of this Response and to credit any overpayment to our Deposit Account No. 03-3125.

Respectfully submitted,

Dated: August 5, 2005

By: _____

Robert D. Katz, Esq.
Registration No. 30,141
Alan J. Morrison, Esq.
Registration No. 37,399
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

Attorneys for Applicants